

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

VANDA PHARMACEUTICALS )  
INC., )  
                ) Plaintiff, )  
                )                ) C.A. No. 18-651 (CFC)  
v.                 )                ) CONSOLIDATED  
                )  
TEVA PHARMACEUTICALS USA, )  
INC., et al., )  
                ) Defendants. )

**JOINT STIPULATION**

Plaintiff Vanda Pharmaceuticals Inc. (“Vanda”), and Defendants Teva Pharmaceuticals USA, Inc. (“Teva”) and Apotex Inc. and Apotex Corp. (“Apotex”) (collectively, “Defendants” and, together with “Vanda,” the “Parties”), through their counsel, hereby stipulate and agree to the following:

WHEREAS, Vanda has asserted, among others, U.S. Patent No. 9,060,995 (“the ’995 patent”), U.S. Patent No. 9,539,234 (“the ’234 patent”), U.S. Patent No. 9,549,913 (“the ’913 patent”), U.S. Patent No. 9,855,241 (“the ’241 patent”), U.S. Patent No. 10,449,176 (“the ’176 patent”), and U.S. Patent No. 10,610,510 (“the ’510 patent”);

WHEREAS, Teva represents and warrants that it holds Abbreviated New Drug Application (“ANDA”) No. 211601, seeking approval from FDA to engage in the commercial manufacture, import, use, sale, or offer for sale of the proposed

generic tasimelteon product that is the subject of ANDA No. 211601 prior to the expiration of the '995 patent, '234 patent, '913 patent, '241 patent, '176 patent, and the '510 patent;

WHEREAS, Apotex represents and warrants that it holds ANDA No. 211607, seeking approval from FDA to engage in the commercial manufacture, import, use, sale, or offer for sale of the proposed generic tasimelteon product that is the subject of ANDA No. 211607 prior to the expiration of the '995 patent, '234 patent, '913 patent, '241 patent, '176 patent, and the '510 patent;

WHEREAS, in the interest of streamlining the issues in the case, Vanda is no longer asserting the '995 patent, '234 patent, '913 patent, '241 patent, '176 patent, and the '510 patent;

NOW THEREFORE:

1. Vanda hereby dismisses its claims with prejudice that the products that currently are the subject of Defendants' ANDAs (specifically, Teva's ANDA No. 211601 and Apotex's ANDA No. 211607) infringe the '995 patent, '234 patent, '913 patent, '241 patent, '176 patent, and/or the '510 patent.

2. Each Defendant hereby dismisses without prejudice any and all counterclaims and challenges concerning the validity and enforceability of the '995 patent, '234 patent, '913 patent, '241 patent, '176 patent, and the '510 patent.

3. Nothing set forth in this stipulation shall be construed as an admission by Vanda that the claims of the '995 patent, '234 patent, '913 patent, '241 patent, '176 patent, and the '510 patent are not infringed.

4. Nothing set forth in this stipulation shall be construed as an admission by Defendants that the claims of the '995 patent, '234 patent, '913 patent, '241 patent, '176 patent, and the '510 patent are valid.

5. The Parties reserve the right to assert any and all claims and defenses in any future proceedings concerning any product other than Defendants' current ANDA products (specifically, Teva's ANDA No. 211601 and Apotex's ANDA No. 211607). For the avoidance of doubt, nothing in this stipulation shall preclude Vanda from asserting any claims of the '995 patent, '234 patent, '913 patent, '241 patent, '176 patent, and/or the '510 patent against any other new or materially modified ANDA product.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

*/s/ Derek J. Fahnestock*

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June 23, 2022

SO ORDERED this \_\_\_\_ day of \_\_\_\_\_, 2022.

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Chief, United States District Judge